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REPORT NO. 813

SKIN LESION THRESHOLD VALUES FOR LASER RADIATION
AS COMPARED WITH SAFETY STANDARDS

(Final Report)

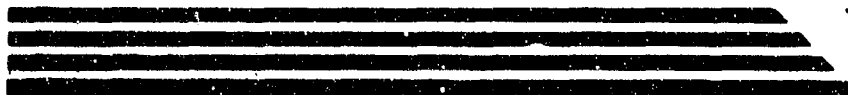
by

Wordie H. Parr, Ph.D.

24 February 1969

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UNITED STATES ARMY
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SKIN LESION THRESHOLD VALUES FOR LASER RADIATION
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(Final Report)

by

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24 February 1969

Cutaneous and Deep Burns Induced by Laser Radiation
Work Unit No. 102
Surgery
Task No. 01
Research in Biomedical Sciences
DA Project No. 3A061102B71R

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ABSTRACT

SKIN LESION THRESHOLD VALUES FOR LASER RADIATION AS COMPARED WITH SAFETY STANDARDS

OBJECTIVE

To compare and evaluate skin injury threshold values with guideline values suggested for safe laser exposure levels.

EXPERIMENTATION

The open literature was reviewed and studies containing skin injury threshold values that were considered pertinent towards establishing acceptable acute laser exposure levels for skin are briefly summarized. Threshold lesion values for both human and animal skin are discussed and compared with guideline values suggested for safe exposure levels.

RESULTS AND CONCLUSIONS

Variations in suggested guideline values illustrate current differences in opinion as to what is considered a safe level for skin exposure. In most cases, laser exposure threshold levels should be further examined and guidelines established for lasers operating at different wavelengths with different time modes.

SKIN LESION THRESHOLD VALUES FOR LASER RADIATION AS COMPARED WITH SAFETY STANDARDS

INTRODUCTION

The large amount of skin surface makes this body tissue readily available to accidental and repeated exposures of laser radiation. Because laser radiation has to be absorbed to produce an effect, any injury produced will depend upon various physical properties of the radiation and of the skin and upon the size of the area exposed. Most laser safety programs include minimal radiation levels for skin exposure, but the values suggested are generally those considered to be non-hazardous under worst case conditions and are not based upon experimental evidence.

Because most concern regarding laser hazards has been with ocular damage and ocular protection, skin exposure data have been meager and have dealt mostly with catastrophic types of damage. Included in the literature, however, are data, although very limited, concerning chronic effects (1) and a few skin studies in which acute injury threshold values are given (2-4). Only the results considered pertinent towards establishing acceptable acute radiation levels for skin exposure are briefly summarized below. The injury threshold values reported are discussed and compared with guideline values suggested for safe exposure levels.

EXPERIMENTATION

Animal Exposure Data

Results of a study by Kuhns, Hayes, Stein and Helwig (2) to establish threshold doses of injury from non-Q-switched ruby laser radiation (2 millisecond pulses) are shown in Table 1. Swine of various pigmentation (Chester Whites, Hampshires, Durocs and miniature pigs) weighing between 10 and 160 kg (22-220 pounds) were used. The back and flanks of the animals were exposed through apertures of 3 to 5 mm diameter that were placed in contact with the skin. The lesions were classified macroscopically and tabulated in three categories:

Slight-diffuse erythema, occurring within 30 seconds to 5 minutes after exposure, drying, slight darkening and scaling of the superficial epidermal layers and slight twisting and bending of the hair stubble. Moderate-pallor in central target area, increased drying, darkening and scaling of the superficial epidermal layers, in addition to increased twisting and bending of the hair stubble and focal melting of some of the tips. Severe-crater formation with central loss of the epidermis, elevation and disruption of the adjacent epidermis, complete ablation of the hair in the target area, coagulation and condensation of the underlying dermis.

The lowest dose producing a slight lesion in the moderately pigmented pig skin was 2.2 joules/cm², whereas 42 joules/cm² were required to produce a slight lesion in the white pig skin. Only a few lesions in the moderate category developed in the pigmented skin. This result may be due to the masking of the dermal pallor by the pigmented skin. Kuhns and his associates point out that this study suggests that highly pigmented skin has an injury threshold about 1/10 the dose of the white skin (2, 3).

Brownell, Parr, Hysell, and Dadrick (4) have produced cutaneous lesions with CO₂ laser radiation ranging from a minimal detectable erythema to tissue coagulation (a white burn). The dose-response relationships for producing these different grades of cutaneous burns were determined for power densities within the range of 0.69 to 13.6 watts/cm² and exposure times of 0.2 to 40 seconds. This range provides

TABLE 1*

Macroscopic Effects of Laser (6943Å) Radiation (Kuhns et al)

LESION	SKIN PIG- MENTATION	INCIDENT DOSE RANGE <small>J./sq.cm.²</small>	NO. OF OBSERVATIONS
No Lesion	Brown	2.2-8	7
	White	8-35	10
Slight	Brown	2.2-43	19
	White	42-190	85
Moderate	Brown	57-73	3
	White	250-800	33
Severe	Brown	200-720	13
	White	1050-1100	5

¹J., Joule's equivalent.

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data for assessing allowable exposure limits, and also provides an insight into what could be expected as a result of an accidental exposure at higher energy levels.

Young Yorkshire pigs with an average weight of 37 pounds (16.8 kg) and free of visible skin pigmentation were used in these studies. The grading system and criteria for evaluating the burns were as follows:

0-No visible change in exposed area

1-Erythema (red burn)

1-1 Erythema disappears within 18-24 hours

1-2 Mild erythema (threshold lesions)

1-3 Moderate erythema

1-4 Severe erythema

2-Coagulation (white burn)

2-1 Spotty coagulation

A threshold lesion as defined in this study does not represent the minimal observed effect following the exposure. Only skin areas showing a perceptible lesion 24 hours later are considered as a positive effect. In almost every instance, either during or immediately following exposure, the skin developed a diffuse, transient erythema that usually extended beyond the limits of the exposed area, but in many cases would disappear shortly afterwards.

Photographs taken immediately and 24 hours after exposure to laser radiation of 2.5 watts/cm² and exposure times of 1.4 to 5.2 seconds are shown in Figures 1 and 2, respectively. Note the diffuse erythema immediately following exposure, shown in the top row of exposed areas (Fig. 1), as compared with the clearly defined lesions shown in the bottom row. The top row of exposures was made approximately 15 minutes later than the bottom row. Erythema that completely faded in 24 hours occurred in the exposed areas shown at the upper right in Figure 2.

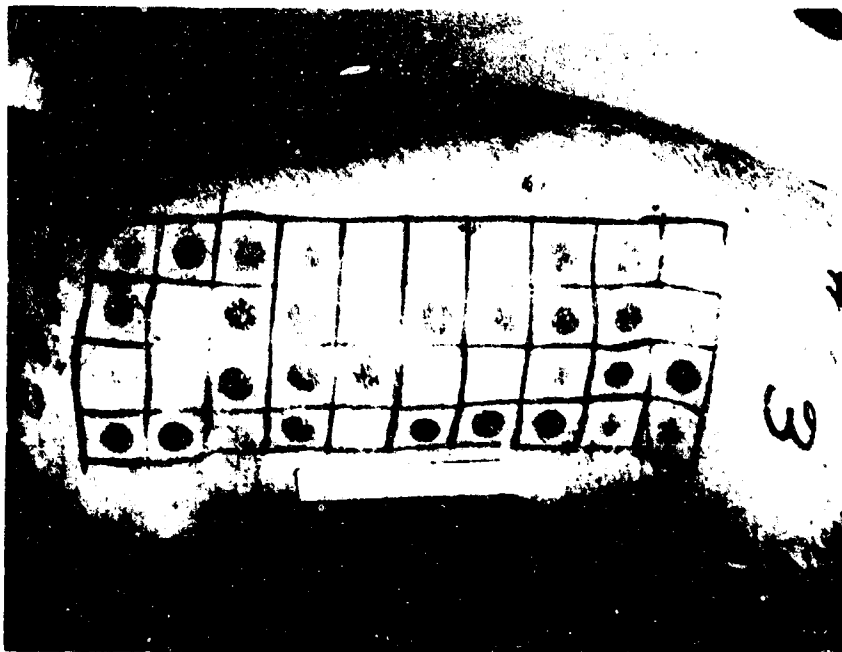


Fig. 1. Porcine skin (Pig No. 23) immediately following exposure to laser radiation of 2.5 watts/cm² and exposure times of 5.2 to 14 seconds.

Data were graphically analyzed by the probit method of Litchfield and Wilcoxon (5) to determine the median effective exposure time (EEt₅₀) for each grade of burn at each irradiance level. The EEt₅₀ is the exposure time for a given irradiance with a 50% probability of producing a given grade of lesions. Table 2 shows the EEt₅₀ for each subdivision of burn severity at each irradiance level used. A total of 2,288 porcine skin burns was evaluated. Lesions of all grades were produced by all irradiance levels except 0.69 watts/cm². In this case, exposure times as long as 41 seconds resulted in only a severe erythematous type of lesions (grade 1-4).

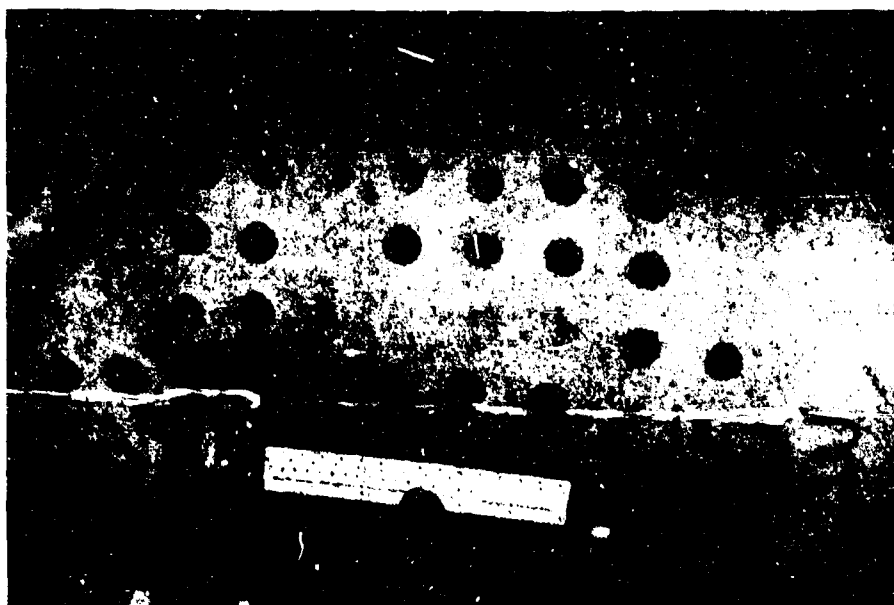


Fig. 2. Porcine skin (Pig No. 23) 24 hours after exposure to laser radiation.

TABLE 2

Median Effective Exposure Times for Different Grades of Burns

MEDIAN EFFECTIVE EXPOSURE TIMES FOR DIFFERENT GRADES OF BURN
AT VARIOUS IRRADIANCE LEVELS.

IRRADIANCE (watts/cm ²)	EEt ₅₀ (sec.)			
	1-2	1-3	1-4	2-1
13.5	22 (20-24)	43 (39-47)	54 (49-59)	66 (61-72)
10.6	30 (28-33)	57 (54-61)	75 (70-80)	91 (87-96)
7.6	37 (32-43)	69 (65-73)	88 (84-92)	111 (107-117)
6.7	71 (65-77)	113 (107-119)	146 (141-151)	177 (172-182)
3.7	113 (107-119)	211 (205-217)	251 (245-257)	291 (285-297)
2.5	213 (207-219)	351 (345-357)	391 (385-397)	431 (425-437)
1.7	411 (405-417)	661 (655-667)	751 (745-757)	841 (835-847)
1.2	741 (735-747)	1081 (1075-1087)	1231 (1225-1237)	14
1.1	1311 (1305-1317)	1721 (1715-1727)	1941 (1935-1947)	23
0.7	1991 (1985-1997)	2671 (2665-2677)	3121 (3115-3127)	3741 (3735-3747)
0.4	3741 (3735-3747)	5701 (5695-5707)	6301 (6295-6307)	7961 (7955-7967)
0.3	6911 (6905-6917)	10211 (10205-10217)	11471 (11465-11477)	-----

A log-log plot of the median effective exposure times (Fig. 3) shows that the slope of the curve for threshold lesions changes at high and at low irradiance levels; curves for the more severe burns show the same general trends. It is evident also that the curves for various grades of burns tend to converge at the longer exposure times, indicating that for long exposure times a relatively small increase in irradiance can mean the difference between a mild and a severe burn.

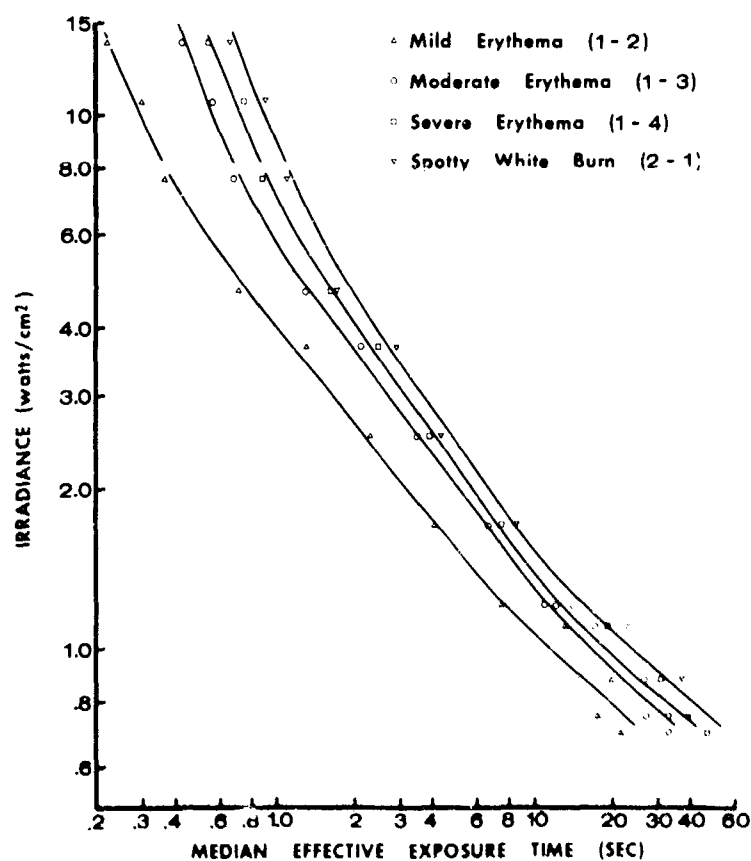


Fig. 3. Median effective exposure times vs. irradiance for thermal skin lesions.

The data plotted to demonstrate the median effective energy density (radiance) as a function of exposure times for 1-2 (mild erythema) and 2-1 (partial white) burns are shown in Figure 4. The apparent plateau on each of the curves at short exposure times suggests that the median effective energy density necessary to produce these lesions will decrease little, if any, as the exposure time is further reduced. If this is the case, then, for exposure times shorter than those shown, the median effective dose (ED_{50}) will be approximately 3 joules/cm² for a mild erythema and 8 joules/cm² for partial white burns.

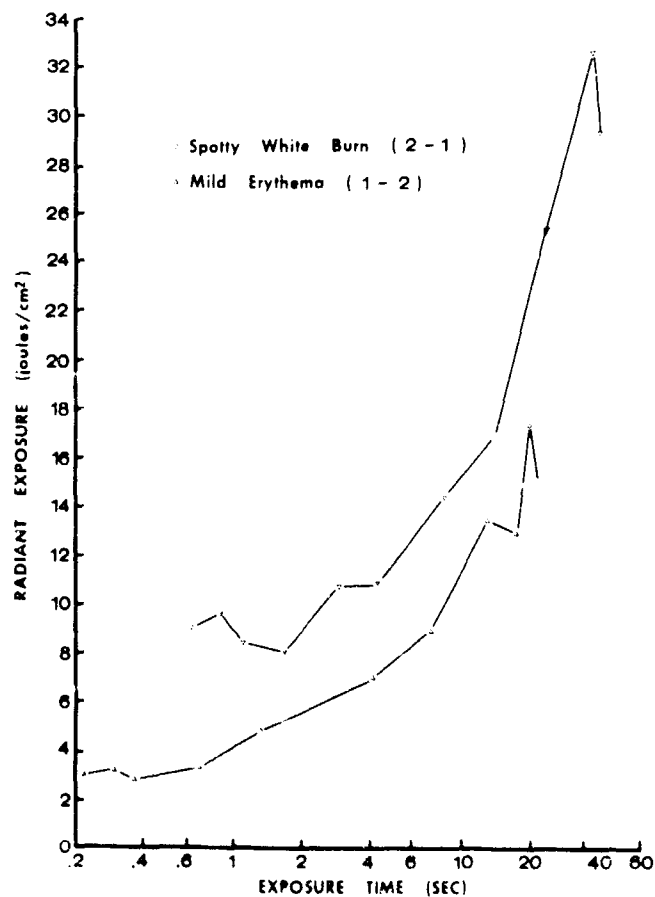


Fig. 4. Radiant exposure as a function of exposure times to produce thermal skin lesions.

Human Exposure Data:

The values offered by Goldman and Rockwell (6) for exposure of human skin to laser radiation are still considered by them to be preliminary even after seven years of research. Nevertheless, they provide a basis for comparisons of data acquired from animal and human exposures.

In Goldman's human skin studies, the surface of the flexor forearm of Caucasian volunteers was used. This area is not covered with hair and usually not affected by sun exposure or other environmental hazards.

Ruby Laser (6943Å):

(1) Normal mode. The minimal reactive dose (MRD) effect was the development of a small red papule, 3-4 mm in diameter, which appeared approximately 2-4 hours post impact and disappeared in 24 hours. The development of a tiny bleeding spot in the center of the papule indicates a reaction beyond the minimal reactive dose. Using a pulse length approximately constant at 0.2 milliseconds, focused ($f = 38$

mm) to a target area which varied from 2.4×10^{-3} to $3.4 \times 10^{-3} \text{ cm}^2$ (0.56 to 0.56 mm diameter), minimal reactions began at a dose of 15-20 joules/cm².

(2) Q-switched mode. An unfocused 10 nanosecond pulse delivering a total of 0.35-0.45 joules in an area approximately 1 cm^2 , produced no noticeable effects. When the beam was focused, energy densities in a range from 0.5-1.5 joules/cm² produced minimal epidermal changes.

Continuous Wave (cw) Lasers:

(1) Helium - Neon Laser (6328Å)--In testing for transillumination, continuous exposure to 75 milliwatts produced no noticeable erythema.

(2) Carbon Dioxide (CO₂) Laser (100,600Å)--One watt/cm² delivered in 4-6 seconds produced a minimal reaction.

(3) Argon Laser (4880Å)--Table 3 shows the experimental conditions and the results obtained from exposure to argon laser radiation. Powers of 0.5 watts and 0.2 watts combined with exposure times from 2 seconds to 10 seconds gave energy densities over an area of $9.5 \times 10^{-2} \text{ cm}^2$ ranging from 4.2 joules/cm² to 52.6 joules/cm². The MRD occurs somewhere between 13 and 17 joules/cm².

TABLE 3

Argon Laser

Reactive dose Caucasian male; Flexor forearm;
Wavelength-488 mm. Beam area: $9.5 \times 10^{-2} \text{ cm}^2$.

<u>Dose(joules/cm²)</u>	<u>Argon Power</u>	<u>Exposure Duration</u>	<u>Reaction</u>
52.6	0.5W	10 sec.	Immediate Erythema
42.1	0.5W	8 sec.	Immediate Erythema
31.6	0.5W	6 sec.	Delayed Erythema
21.1	0.5W	4 sec.	Erythema, one hour
21.1	0.2W	10 sec.	Erythema, one hour
16.8	0.2W	8 sec.	Erythema, one hour
12.6	0.2W	6 sec.	No visible Erythema
10.5	0.5W	2 sec.	No visible Erythema

Conclusion: Reactive dose for Argon Laser
lies between 13 and 17 j/cm².

Goldman et al

DISCUSSION AND CONCLUSION

Comparison of Human and Animal Data:

To simplify for comparison purposes, the reported threshold values for skin injury by different types of laser radiation for both humans and animals are listed in Table 4.

TABLE 4

Injury Threshold Values for Skin from Laser Energy

<u>LASER</u>	<u>Goldman et al</u> (Human)	<u>Kuhn et al</u> (Pig)	<u>Brownell et al</u> (Pig)
1. Ruby			
A. <u>NORMAL MODE</u>			
Non-pigmented	15-20 j/cm ²	42-190 j/cm ²	_____
Pigmented	_____	2.2-43 j/cm ²	_____
B. <u>Q-SWITCHED</u>	0.5-1.5 j/cm ²	_____	_____
2. Argon	13-17 j/cm ² (6 sec)	_____	_____
3. CO ₂	4-6 j/cm ² (4-6 sec)	_____	3 j/cm ²

A comparison of values for normal mode ruby laser irradiation shows that the upper limit of the threshold exposure value reported for Caucasian skin (15-20 joules/cm²) is about one-half of the lower limit (42-190 joules/cm²) reported for non-pigmented pig skin. This difference might be attributed to the size of the laser areas, and to such biological factors as variations in pigmentation, thickness in epidermis and a possible variable vascular response. The optical and thermal properties of pig and human skin are similar (7, 8).

Although data isn't available for the exposure of highly pigmented human skin to ruby laser radiation, Goldman, during a laser safety conference discussion (9), estimated that such pigmented skin had an injury threshold approximately one-fifth to one-tenth that of Caucasian skin. This relationship agrees favorably with the values reported by Kuhns et al (2, 3) from their pig studies. On the basis of this pigmented to non-pigmented skin relationship, the injury threshold value for heavily pigmented human skin might be considered to be one-tenth of the lower limit of the value for non-pigmented skin, or 1.5 joules/cm². This

value is reasonably consistent with the experimental value of 2.2 joules/cm² reported for pigmented porcine skin (2).

The values shown for human and swine exposure to CO₂ laser radiation are quite similar (approximately 1 watt/cm²). The differences that exist could well be attributed to the criteria established to determine a threshold lesion. In the studies by Brownell et al (4), threshold values were given for four different levels of erythema, of which only the most severe type might be considered a serious injury.

Guideline and Threshold Values:

Guideline values suggested for safe exposure levels by several agencies are shown in Table 5. The variations in these suggested values illustrate current differences in opinion as to what is considered a safe level for skin exposure.

TABLE 5
Suggested Laser Guidelines for Skin Protection

Laser Radiation	A	B	C	D	E	F
Q-Switched Ruby (6943Å) (joules/cm ²)		.042	.001			.005
Normal Pulsed Ruby (6943Å) (joules/cm ²)		.5	.01			.05
Continuous Laser (U-V Excepted) (watts/cm ²)		1.5	.1	1.	1.	*5
Total Incident Energy Per Second (joules/cm ²)	≤ .1					
Pulsed Lasers (joules/cm ²)				.1	.1	

A - Code of Practice, British Ministry -1965

B - USA Environmental Health Agency - 1966

C - Am Industrial Hygiene Association Meeting - 1967

D - AEC Nevada Test Site - 1968

E - Laser Safety Conference, Cincinnati, Ohio - 1968

F - Am Conference, Governmental Industrial Hygienists - 1968

* white light wavelengths

Calculations based on experimental evidence for minimal acute injury (Table 4), including a factor of ten for safety, indicate that 0.15 joules/cm², for normal mode ruby laser radiation, could be an acceptable level for allowable exposures of pigmented skin (a worst case condition). Similarly, an allowable level for Q-switched exposures would be 0.015 joules/cm². In both of these cases, the levels are considerably higher than those generally suggested in laser guideline recommendations. The levels, however, for Q-switching should be further studied and established through experimentation.

Guidelines, as seen in Table 5 for cw laser radiation, cover a range from 5 to 0.1 in power density. These maximum allowable exposure levels, in most cases, include all cw lasers, although the CO₂ laser is generally considered the most hazardous. Data in Table 4 suggest that differences in allowable exposure levels is desirable. This arrangement would give greater leeway in the use of different types of cw lasers. In the case of the CO₂ laser, a permissible radiation exposure level for the skin could be as high as 1 watt/cm². The possibility of acute injury by overexposure would be minimized by a cue such as a sensation of warmth in combination with the avoidance reaction time. Furthermore, according to Goldman's preliminary studies, a safety value two to three times greater than that allowable for CO₂ laser radiation appears to be appropriate for exposure to an argon laser. However, the small spot size used in the argon laser exposures could be partly responsible for the high MRD as compared with that of the CO₂ laser.

Research on skin exposure should be current for available laser devices and guidelines should be established for lasers operating at different wavelengths with different time modes. Such an arrangement would provide both personnel safety and minimal operational hindrance.

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